K121187

SEP 17 2012

5 510(k) Summary

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Date Prepared: July 16, 2012

Device Trade Name: Katalyst Laser Probes & Illuminated Laser Probes

Common Name: Ophthalmic Laser

Classification: 21 CFR 886.4390; Ophthalmic Laser

Class: II

Product Code: HQF, HQB, MPA

Indications For Use:
Laser Probes and Illuminated Laser Probes:

For use in vitreoretinal surgery to perform endo-ocular laser photocoagulation treatments at operating wavelength of 500nm to 900nm.

Device Description:
The laser probes are cables made out of one fiberoptic, one laser connector, one handle for surgeon manipulation, stainless steel tubing extending from the handle which penetrates into the surgical site, and protective sheath over the fiber.

The illuminated laser probes (referred to also as "laser/illumination probes") are cables made out of two fiberoptics (one for laser and one for illumination), one laser connector, one illumination connector, one handle for surgeon manipulation, stainless steel tubing extending from the handle, and protective sheath over both fiberoptics.

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On one side, the distal side, the fiberoptic is terminated by a connector that attaches to the machine, be it laser or illumination. On the other side, it is terminated by a stainless steel tubing which penetrates into the eye, and may be 20g, 23g, or 25g in size in case of laser probes, or 20g in case of laser/illumination probes.

The fiber for laser transmission is made out of glass, and is restricted for use within the wavelength range of 500nm to 900nm. The fiber for illumination is made out of either glass or plastic. The tubing is provided in two shapes, referred to as straight or curved. The configuration is chosen based on the surgeon requirements. The total length of the device is 10 feet.

In case of laser and illumination functionalities provided by the same probe, the common protective sheath runs for 1 foot, while both branches run for 9 feet with each branch having its own protective sheath and each branch ending with its own connector. The same tubing will then hold within its internal diameter the laser fiber and the illumination fiber.

Predicate Devices:
The Katalyst Illuminated Laser Probe was shown to be substantially equivalent to the previously cleared devices (K050807 and K021696).

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Substantial Equivalence:

SUMMARY OF EVALUATION

Bench testing performed on this device and compared to the predicate indicates that the Katalyst Illuminated Laser Probes and Laser Probes are substantially equivalent to predicate devices. Bench testing of the Katalyst Illuminated Laser Probes and Laser Probes was performed in accordance with FDA Guidance on the Content and Organization for a Medical Laser. Biocompatibility testing was performed in accordance with ISO 10993. Sterilization development, validation, and control were performed in accordance with ISO 11135-1. Product shelf-life was established in accordance with ASTM Standard #F 1980-09 (2011) and packaging integrity was established in accordance with ASTM F 1929-04 and ASTM F88/F88M-09. Optical radiation safety testing was performed in accordance with ISO 15752 and ISO 15004-2.

SUMMARY OF EQUIVALENCE

FDA File Reference No.	510(k) No. K021696 for Laser	510(k) No. K050807 for Illumination
TECHNOLOGICAL CHARACTERISTICS	Comparison Result	Comparison Result
Indications for Use	Identical	Identical
Target Population	Identical	Identical
Design	Similar	Similar
Optical Output	Identical	Identical
Materials	Identical	Identical
Performance	Identical	Identical
Sterility	Identical	Identical
Biocompatibility	Identical	Identical
Anatomical Sites	Identical	Identical
Human Factors	Identical	Identical
Energy Used and/or Delivered	Similar	Similar
Compatibility with Environment and Other Devices	Identical	Identical
Where Used	Identical	Identical
Standards Met	Identical	Identical
Electrical Safety	Identical (not applicable)	Identical (not applicable)
Thermal Safety	Identical (not applicable)	Identical (not applicable)
Radiation Safety	Identical (not applicable)	Identical (not applicable)

Design: The tip configuration is straight for the predicate devices and the tip configuration may be straight or curved for the Katalyst Laser and Illuminated Laser Probes ("Probes"). The difference in design between the curved tips of the Probes and the straight tips of the predicate devices does not affect the safety or effectiveness of the Probes when used as indicated.

The only difference between the straight tip predicate device and the curved tip Probe is that the curved tip Probe may aim the distal end of an optical fiber in a curved direction

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within the inner eye and the straight tip predicate device may aim the distal end of an optical fiber in a straight direction within the inner eye. Compared to the straight tip predicate device, the curved tip Probe: (1) does not allow a surgeon to aim the distal end of an optical fiber at different tissues or types of targets within the inner eye; (2) does not allow a surgeon to perform a different surgical procedure; and (3) does not change the manner that a surgeon may perform a surgical procedure. There is no difference in safety or effectiveness of the straight tip predicate device and the curved tip Probe.

The curved tips of the Probes do not present any inherent safety risk that is not also inherent in a straight tip of the predicate devices. The interface between the device connectors and the illumination or laser machine connectors is identical for Probes with curved tips and predicate devices with straight tips. The optical properties of optical fibers in straight tips of the predicate devices are identical to the optical properties of optical fibers in curved tips of the Probes.

The 510(k) presented the design of the curved tube used for Probes with curved tips and the design of the straight tube used for Probes with straight tips. The straight tubes and the curved tubes are: manufactured from the same material, manufactured with the same inner and outer dimensions, and manufactured at the same overall length. The only between the curved tube and the straight tubes is that the distal end of the curved tubes extends 1.3 inches from the tube proximal end and the distal end of the straight tubes extends 1.4 inches from the tube proximal end. This difference in length is a result of the curved tube being curved, i.e., if a curved tube would be mechanically straightened then the distal end of that straightened tube would extend 1.4 inches from the tube proximal end. This difference does not affect the safety or effectiveness of the Probes.

Energy Used and/or Delivered: The operating range is similar but not identical to the predicate devices. The operating range of the Katalyst Laser and Illuminated Laser Probes ("Probes") is wavelengths of 500 nm to 900 nm. The operating range of the predicate devices is wavelengths of 500 nm to 1100 nm. The difference between the upper limit of operating wavelength of the Probes and the upper limit of operating wavelength of the predicate devices does not affect the safety or effectiveness of the Probes because the upper limit of the wavelength operating range of the Probes falls within the wavelength operating range of the predicate devices.

Conclusion

The Katalyst Illuminated Laser Probes and Laser Probes were shown to be substantially equivalent to previously cleared devices with respect to intended use, indications for use, technological characteristics, performance characteristics, and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 17 2012

Katalyst Surgical, LLC
c/o Ms. Michelle McDonough
Associate, Regulatory Affairs
1331 H St NW, 12th Floor
Washington, DC 20005

Re: K121187
Trade/Device Name: Katalyst Laser and Illuminated Laser Probes
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: II
Product Code: HQF, HQB, MPA
Dated: August 31, 2012
Received: September 5, 2012

Dear Ms. McDonough:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jessica Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use

510(k) Number (if known): K121187

Device Name: Katalyst Laser Probes and Illuminated Laser Probes

Laser Probes and Illuminated Laser Probes:

For use in vitreoretinal surgery to perform endo-ocular laser photocoagulation treatments at operating wavelength of 500nm to 900nm.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K121187